

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/
FENFLURAMINE/DEXFENFLURAMINE)
PRODUCTS LIABILITY LITIGATION

MDL NO. 1203

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

v.

AMERICAN HOME PRODUCTS
CORPORATION

NO. 99-20593

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8444

Bartle, C.J.

March 31, 2010

The Estate of Harry T. Britton, Jr. (the "Estate" or "representative claimant"), a representative claimant under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether the Estate has demonstrated a reasonable medical basis to support its claim for Matrix Compensation Benefits ("Matrix Benefits").³ To seek

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Mary L. Britton, Harry T. Britton's ("Mr. Britton" or "decedent") spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify for
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Matrix Benefits, a representative claimant⁴ must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The representative claimant completes Part I of the Green Form. Part II is completed by an attesting physician who must answer a series of questions concerning the deceased's medical conditions that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, if the representative claimant is represented by an attorney, the attorney must complete Part III.

In June, 2006, Mary L. Britton ("Ms. Britton"), Administrator of the Estate of Harry T. Britton, submitted an amended Green Form to the Trust signed by the attesting

3. (...continued)
compensation purposes Diet Drug Recipients based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to the Diet Drug Recipient's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to representative claimants where the Diet Drug Recipients are diagnosed with serious VHD, they took the drugs for 61 days or longer, and they did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to representative claimants where the Diet Drug Recipients were registered as having only mild mitral regurgitation by the close of the Screening Period, they took the drugs for 60 days or less, or they were diagnosed with conditions that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Under the Settlement Agreement, representative claimants include estates, administrators or other legal representatives, heirs or beneficiaries. See Settlement Agreement § II.B.

physician, Alan H. Younes, M.D., F.A.C.C., F.S.C.A.I.⁵ Based on an echocardiogram dated April 22, 1999, Dr. Younes attested in Part II of the Green Form that Mr. Britton suffered from severe mitral regurgitation, moderate aortic regurgitation, and death resulting from a condition caused by valvular heart disease or valvular repair/replacement surgery.⁶ Based on such findings, the Estate would be entitled to Matrix B-1,⁷ Level V benefits in the amount of \$253,732.⁸

In September, 2006, the Trust forwarded the claim for review by Craig M. Oliner, M.D., one of its auditing

5. Ms. Britton submitted the original Green Form in May, 2003. In the amended Green Form, Ms. Britton sought Matrix Benefits on Matrix B, and Dr. Younes changed the date of the echocardiogram on which the Green Form is based.

6. Dr. Younes also attested that Mr. Britton suffered from an abnormal left atrial dimension, a reduced ejection fraction of less than 30%, the presence of ACC/AHA Class I indications for surgery to repair or replace the aortic and/or mitral valve(s) where such surgery was medically contraindicated, and the presence of New York Heart Association Functional Class III symptoms. These conditions, however, are not at issue in this claim.

7. Mr. Britton ingested Diet Drugs for less than 61 days. Thus, if eligible for benefits, the Estate only would be entitled to payment based on Matrix B-1. See Settlement Agreement § IV.B.2.d.(2)(b). The Estate concedes that its claim is on Matrix B-1.

8. Under the Settlement Agreement, a claimant or representative claimant is entitled to Level V Matrix Benefits if the Diet Drug Recipient suffered "[d]eath resulting from a condition caused by valvular heart disease or valvular repair/replacement surgery which occurred post-Pondimin® and/or Redux™ use supported by a statement from the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist, supported by medical records." Settlement Agreement § IV.B.2.c.(5)(c).

cardiologists.⁹ In audit, Dr. Oliner concluded that there was no reasonable medical basis for the attesting physician's representation that Mr. Britton died as a result of a condition caused by VHD. Specifically, Dr. Oliner explained:

The patient did not have valve surgery. The patient died 1/24/01. He was admitted 1/23/01 with "cardiogenic pulmonary edema" thought secondary to [Atrial] Fibrillation with a rapid ventricular rate due to a hypertensive cardiomyopathy. Other records suggest a tachycardia induced cardiomyopathy due to a rapid heart rate during atrial fibrillation. A 1/23/01 echo reportedly shows a [left ventricular ejection fraction of] 20-25% with mild [aortic regurgitation] and mild [mitral regurgitation]. There is no data in the medical records to suggest heart valve disease as the cause of death. A 6/5/98 echo showing severe [left ventricular] dysfunction ([ejection fraction] 15-20%) with mild-moderate [mitral regurgitation] suggests that the [mitral regurgitation] did not cause the cardiomyopathy.¹⁰

Based on Dr. Oliner's finding that there was no reasonable medical basis for the attesting physician's representation that Mr. Britton died as a result of a condition caused by VHD, the Trust issued a post-audit determination denying the Estate's claim. Pursuant to the Rules for the Audit

9. Pursuant to Pretrial Order ("PTO") No. 3882 (Aug. 26, 2004), all Level III, Level IV, and Level V Matrix claims are subject to the Parallel Processing Procedures ("PPP"). As Wyeth did not agree that the Estate had a Level V claim, pursuant to the PPP, the Trust audited the Estate's claim.

10. Dr. Oliner also found that there was no reasonable medical basis for the attesting physician's determination that decedent suffered from severe mitral regurgitation. The only issue, however, is whether the representative claimant is entitled to Level V benefits.

of Matrix Compensation Claims ("Audit Rules"), the Estate contested this adverse determination.¹¹ In contest, the Estate argued that while the auditing cardiologist concluded that Mr. Britton's medical records did not support the conclusion that VHD was the cause of death, the proper question was whether Mr. Britton's death was the result of a condition caused by VHD. The Estate also submitted a declaration by Dr. Younes, who explained:

Regarding cause of death, it is well documented in the medical literature that there is an entity called tachycardia induced cardiomyopathy. [Mr. Britton] had [atrial fibrillation] with uncontrolled ventricular rate since 1998, and the association of mitral regurgitation and [atrial fibrillation] is well documented as mitral regurgitation causes increasing left atrial dilation. It is difficult to know with absolute certainty whether the mitral regurgitation caused [left ventricular dysfunction] or the other way around; but, given the history of uncontrolled ventricular rate since 1998, it is more likely that the cardiomyopathy worsened due to tachycardia which was caused by left atrial dilation due to mitral regurgitation. Actually, development of [atrial fibrillation] in the presence of moderate mitral regurgitation is an indication to proceed with [mitral valve replacement] or repair. Therefore, it is probable that this man's death resulted from a condition caused by valvular heart disease.

11. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to the Estate's claim.

Subsequently, the Estate submitted a statement from the attending cardiologist at the time of Mr. Britton's death, Christopher L. Ingram, M.D., F.A.C.C., F.A.C.P., who opined:

It is my professional opinion that the patient had moderate to severe mitral regurgitation that was physiologically significant contributing to the patient's death in conjunction with co-morbid illnesses. Therefore, this patient's death resulted from a condition caused by valvular heart disease, in association with other medical conditions.

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Oliner submitted a declaration in which he again concluded that there was no reasonable medical basis for the attesting physician's finding that Mr. Britton died as a result of a condition caused by VHD. Specifically, Dr. Oliner stated:

According to the medical records, [Mr. Britton] died of cardiogenic pulmonary edema thought secondary to atrial fibrillation with a rapid rate due to a hypertensive cardiomyopathy. Other records suggest a tachycardia-induced cardiomyopathy due to a rapid heart rate during atrial fibrillation. At no point in [decedent's] medical records do [his] physicians indicate that [he] had mitral regurgitation induced cardiomyopathy. The fact that [Mr. Britton's] June 5, 1998 echocardiogram reportedly showed severe left ventricular dysfunction and only mild mitral regurgitation is strong evidence that the cardiomyopathy was not due to mitral regurgitation. That is confirmed by the January 23, 2001 echocardiogram, which reportedly showed severe left ventricular dysfunction with mild [mitral regurgitation]. To the extent that [Mr. Britton] had mitral regurgitation, this appears secondary to the cardiomyopathy. In addition, a July 22, 1998

Natchitoches Parish Hospital "Personal History" states that [Mr. Briton's] cardiomyopathy had existed for at least two years previously, suggesting that [his] cardiomyopathy preceded the use of diet drugs.

The Trust then issued a final post-audit determination, again denying the Estate's claim. The Estate disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the Estate's claim should be paid. On July 13, 2007, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7313 (July 13, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. The Estate then served a response upon the Special Master. The Trust submitted a reply on October 19, 2007, and the Estate submitted a sur-reply on November 9, 2007. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor¹² to review claims after the Trust

12. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two
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and the Estate have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and the representative claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether the Estate has met its burden in proving that there is a reasonable medical basis for the attesting physician's finding that Mr. Britton died as a result of a condition caused by VHD. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in the Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of its claim, the Estate repeats the arguments it made in contest. In addition, the Estate argues that the results of Mr. Britton's January 23, 2001 echocardiogram are not reliable. The Estate relies on the statement of Dr. Younes, in which he explains:

12. (...continued)
outstanding experts who take opposite positions" is proper. Id.

There was an echocardiogram performed in 2001, the day before this man's death and the echo report indicates mild mitral regurgitation; however, this determination is questionable because it is highly unlikely that this man's untreated severe or even moderate regurgitation in 1999 would become mild in 2001, when his heart got larger with more left atrial dilation.

In addition, the Estate relies on the statement of Dr. Ingram, in which he explains that the "echo on 1/23/01 was suboptimal as noted under the impression #5, qualifying the study with poor acoustic windows limiting data acquisition; therefore this echo is not reliable."

In response, the Trust argues that the Estate has the burden of proving that there is a reasonable medical basis for the Green Form representation at issue. The Trust also asserts that Mr. Britton did not die from a condition caused by VHD because, according to Dr. Oliner, the medical records "suggest that [Mr. Britton] suffered from severe left ventricular dysfunction **prior** to developing moderate mitral regurgitation, indicating that [Mr. Britton's] 'condition' resulted from some cardiomyopathy **other than** valvular heart disease." (emphasis in original). In addition, the Trust notes that the Death Summary indicates Mr. Britton's cause of death was "[e]nd stage cardiomyopathy." Finally, the Trust argues that Dr. Oliner's conclusion is supported by Mr. Britton's medical records, which indicate that he had a history of atrial fibrillation with associated cardiomyopathy since 1996.

In its sur-reply, the Estate reiterates its position that the issue for resolution is whether Mr. Britton died from a condition caused by VHD, not decedent's level of mitral regurgitation. The Estate, for the reasons expressed in its response, asserts that it is entitled to Level V Matrix Benefits.

The Technical Advisor, Dr. Vigilante, reviewed Mr. Britton's echocardiogram and medical records and concluded that there was no reasonable medical basis for the attesting physician's representation that Mr. Britton died as a result of a condition caused by VHD. Dr. Vigilante explained:

[Mr. Britton's] death did not result from a condition caused by valvular heart disease or valvular repair/replacement surgery. Mr. Britton did not have valve surgery. It is well documented in the medical records that he had severe dilated cardiomyopathy for several years prior to his death on January 24, 2001. This cardiomyopathy predated the presence of significant mitral regurgitation as noted in the medical records. His treating cardiologist, Dr. Ingram, stated in the medical records that his congestive heart failure and atrial fibrillation were due to a severely depressed hypertensive cardiomyopathy. The cause of death was documented to be an end-stage cardiomyopathy. Mr. Britton's mitral regurgitation was secondary to his severe cardiomyopathy with a very low ejection fraction that had been noted to be present for a number of years. Therefore, [Mr. Britton's] death resulted from his cardiomyopathy and not valvular heart disease.

After reviewing the entire Show Cause Record, we find the Estate's arguments are without merit. As an initial matter, the Estate failed to challenge the auditing cardiologist's and

Technical Advisor's conclusions that Mr. Britton suffered severe dilated cardiomyopathy prior to suffering any significant mitral regurgitation.¹³ Specifically, Dr. Oliner explained that a "Personal History" completed at Natchitoches Parish Hospital on July 22, 1998 indicated that decedent's cardiomyopathy had existed for at least two years, which suggests that Mr. Britton's cardiomyopathy preceded the ingestion of Diet Drugs. In addition, Dr. Vigilante concluded that Mr. Britton's cardiomyopathy "predated the presence of significant mitral regurgitation as noted in the medical records." On this basis alone, the Estate has failed to meet its burden of demonstrating that there is a reasonable medical basis for the attesting physician's representation at issue.

In addition, we reject the Estate's argument that the equivocal conclusions of Dr. Younes and Dr. Ingram satisfy the criteria for Level V Matrix Benefits. Specifically, Dr. Younes stated that "it is probable that this man's death resulted from a condition caused by valvular heart disease." In addition, Dr. Ingram opined:

It is my professional opinion that the patient had moderate to severe mitral regurgitation that was physiologically significant contributing to the patient's death in conjunction with a co-morbid illness. Therefore, this patient's death resulted from a condition caused by valvular heart disease, in association with other medical conditions.

13. Despite an opportunity to do so, the Estate did not submit a response to the Technical Advisor Report. See Audit Rule 34.

The Settlement Agreement specifically provides that a claimant or representative claimant will receive Level V Matrix Benefits if the Diet Drug Recipient suffered "death resulting from a condition caused by valvular heart disease." Under this definition, the opinion of Dr. Younes that it is "probable" that Mr. Britton died from a condition caused by VHD and the opinion of Dr. Ingram that mitral regurgitation "contribut[ed]" to Mr. Britton's death are insufficient to qualify the Estate for Level V Matrix Benefits.

For the foregoing reasons, we conclude that the Estate has not met its burden of proving that there is a reasonable medical basis for finding that Mr. Britton's death resulted from a condition caused by VHD. Therefore, we will affirm the Trust's denial of the Estate's claim for Matrix Benefits and the related derivative claim submitted by Mr. Britton's spouse.